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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,101	04/01/2005	Kristjan S Gudmundsson	PU4959USW	7560

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,101	<b>Applicant(s)</b> GUDMUNDSSON ET AL.	
	<b>Examiner</b> Venkataraman Balasubramanian	<b>Art Unit</b> 1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,9-17,19 and 20 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 13 is/are allowed.
- 6) ☒ Claim(s) 14-16,19 and 20 is/are rejected.
- 7) ☒ Claim(s) 1-6, 9-12 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicants' response, which included cancellation of claims 7, 8, 18 and 21-22 and amendment to claims 1, 13, 17, 19 and 20, filed on 2/8/2006, is made of record. Claims 1-6, 9-17, 19 and 20 are now pending. In view of applicants' response, 112 second paragraph rejection of "physiologically functional derivative" is deemed as obviated and rejection of claim 22 is rendered moot. In addition, 112 first paragraph rejection of scope of enablement of solvate is also obviated. Furthermore, the prior art rejections over Thomas et al. have been obviated. However, the 112 second paragraph rejection of claim 14 remains. Following additional new grounds of rejections in view of applicants' amendment apply.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-16, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim and share the same limitation

1. Claim 14 is indefinite as it appears to be a pharmaceutical composition but does not recite any other ingredient. A composition claim should have more than one ingredient.

This rejection is same as made in the previous office action. Applicants' traversal is not persuasive.

First of all, a composition should have more than one ingredient. Claim 14 does not recite any other ingredient. Applicants are relying on the comprising language and had argued that the composition can include besides a compound of formula 1, any ingredient at all. See response, page 10 first paragraph.

Recitation of the phrase "comprising" renders this claim indefinite as the term is open-ended and can include more than what is being positively recited therein. See MPEP 2111.03 which states: The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts").

Therefore, if one were accept applicants' assertion that this claim includes any other ingredients, then the claim 14 is to interpreted as "compound of claim 1 + any or all ingredients of the universe of composition". Granting this if one were to examine claim 15 and 16, it would appear that claim 15 would be "compound of claim 1 + any or

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all ingredients of the universe of composition + a pharmaceutically acceptable carrier or diluent” and claim 16 would be “compound of claim 1 + any or all ingredients of the universe of composition + an antiviral agent selected from the group consisting of acyclovir and valaciclovir or a pharmaceutically acceptable salt thereof”. Thus it is clear any or all ingredients of the universe of composition do not include a pharmaceutically acceptable carrier or diluent of claim 15 and an antiviral agent selected from the group consisting of acyclovir and valaciclovir or a pharmaceutically acceptable salt thereof of claim 16. Thus, it is not clear what is included and what is excluded by the term comprising in claim 14. Hence, claim 14 fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As for appeal, the case laws cited in the above passage is relied on along with the interpretation.

2. The currently amended claim 19 is a duplicate of claim 17 as there is no material difference except for the wording between claim 17 and claim 19. If the scope of claim 19 is different from claim 17, then applicants should show what the difference is and indicate where in the specification the support for the different scope is provided.

3. Claim 20 is indefinite as it recites a process of preparing compound of formula I but limits the  $R^3$  and  $R^4$  choices.  $R^3$  and  $R^4$  choices do not match with those of claim 1. Note the  $R^3$  and  $R^4$  choices of claim 1 are broader than that of claim 20. Thus, it is not clear how one would arrive at compound of formula I recited in claim 1 from the process of claim 20 with limited  $R^3$  and  $R^4$  choices to broader choices of  $R^3$  and  $R^4$  choices in claim 1.

***Allowable Subject Matter***

Claim 13 is allowed. Claims 1-6 , 9-12 and 17 are objected to but, barring finding of any prior art in a subsequent search and deletion of a proviso at the last but one line of claim relating non-elected subject matter, would be allowable.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for

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the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

*Venkataraman Balasubramanian*  
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4/29/2006